

REMARKS

Claims 1, 2, 4, 5, 8, 9, 13, 14, 16, 17, 19, and 136-139 remain pending. The Office has allowed claim 136. Claims 6-7, 10-12, 15, 18, 20-135, and 140-158 have been cancelled.

Claim 1 has been amended to clarify the identity of the Z_1 and Z_4 terminal blocking group alternatives. The amended claim 1 makes it apparent that the N- of Z_{11} is the amino terminus of the adjacent amino acid and the -C(O)- of Z_{14} is a portion of the carboxy terminus of an adjacent amino acid. Claim 13 has been amended to retain consistency with the amended claim 1. Similarly, claim 16 has been amended to clarify the identity of the Z_{11} and Z_{14} terminal blocking group alternatives, similar to amended claim 1. Claim 17 has been amended to retain consistency with the amended claim 16. These amendments are supported by the Specification at page 35, lines 5-15.

Claim 1 has also been amended to remove the peptide analog alternative from Z_2 and Z_3 . The addition of "first peptide sequence" and "second peptide sequence" in claim 1 was made to amplify the antecedent basis of the peptide sequence at Z_2 and Z_3 , and to more easily distinguish these positions from the larger mimic peptide of which they are part. Similar amendments were made to claim 16. Also in regards to Z_2 and Z_3 , the "optional" terminology has been removed in favor of specifying these positions as bonds—no change in the scope of the claims is introduced because, essentially, when the "optional" Z_2 peptide is not in place, this position is a bond connecting X_1 and Z_1 (or Z_3 connecting X_{10} and Z_4). Claim 13 has been amended to be consistent with these changes to claim 1. Similarly, claim 16 has been amended to remove the peptide analog alternative and "optional" terminology from Z_{12} and Z_{13} , with claim 17 amended to retain consistency with claim 16.

Claims 137 and 138 have been amended for reasons discussed below.

A. NEW MATTER REJECTION

On page 3 of the 5/5/04 Office Action, the Office asserts that claims 1 and 16 contain new matter not supported by the specification and thereby fails to comply with

the written description requirement. Claims 1 and 16 have been amended so that Z_2 and Z_3 are either 1 to 5 residue peptides or bonds (*i.e.*, the positions contain from zero to 5 amino acid residues), effectively canceling the combination of peptide and peptide analog that the Office objected to. Therefore, amended claims 1 and 16 do not contain new matter.

On page 3 of the 5/5/04 Office Action, the Office asserts that claims 137 and 138 contain new matter not supported by the specification, but the **Office refers to a specification citation other than that provided by Applicant**. Claims 137 and 138, as amended, are reproduced here for the convenience of the Office:

Claim 137: An isolated compound which inhibits pilus assembly, the compound consisting essentially of SEQ ID NO: 12, wherein the compound is a mimic of an amino terminal motif of a pilus subunit.

Claim 138: An isolated compound which inhibits pilus assembly, the compound comprising a mimic of an amino terminal motif of a pilus subunit, wherein the mimic comprises SEQ ID NO:12.

In the 2/4/04 Response to Office Action, Applicant stated that "Claims 137-138 find support in the specification at pages 35-37."¹ Pages 35-37 recite preferred sequences "*comprising* formula (I)."² Table 2 makes clear that listed sequences, which include SEQ ID NO:12, are "subunit N-terminal-motif-derived peptides," thereby rebutting the Office's assertion that the cited pages lack the amino terminal motif limitations of newly added claims 137 and 138.

The Office also asserts that the cited support requires the compound to contain two alternating hydrophobic residues. But neither the recitation of the requirements of formula (I)³ nor the listing of preferred sequences⁴ require alternating hydrophobic residues.

¹ 2/4/04 Response to Office Action, p. 15.

² Specification, p. 35, ln. 16-17.

³ Specification, p. 32, ln. 19 – p. 33, ln. 7.

⁴ Specification, p. 35-37; Table 2.

The Office further asserts that that the cited support lacks the mimic of a chaperone G₁ beta-strand as now in claims 137 and 138. A "mimic of a chaperone G₁ beta-strand" has been cancelled from claims 137 and 138 and, thus, the rejection is now moot.

The Office asserts that competitive binding to a pilus subunit hydrophobic groove, as recited in claim 139, is not supported in the specification. But the specification describes a pilus subunit **groove as the binding site** for a mimic of an amino terminal motif⁵ and explains that this subunit **groove is hydrophobic** in character.⁶ Furthermore, the specification makes it clear that the **peptide of claim 139 binds to this groove in a competitive fashion**.⁷ So, the recital of competitive binding of a peptide comprising SEQ ID NO: 12 to a pilus subunit hydrophobic groove is supported by the specification and is not new matter.

As such, Applicant traverses and respectfully requests the Office to withdraw the new matter rejections.

B. REJECTION OF CLAIMS UNDER 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1, 2, 4, 5, 8, 9, 16, 19, and 137-139 under 35 U.S.C. §102(b) as being anticipated by Flemmer et al. To satisfy prima facie anticipation, a reference must teach, expressly or inherently, each and every element required by a claim as interpreted by one of ordinary skill in the art.⁸

⁵ Specification, p. 6, ln. 7-9 (disclosing that "the present invention is directed to isolated and purified compounds and synthesized *compounds which bind to a pilus subunit groove* and thus inhibit pilus assembly")

⁶ Figure 1C depicts the hydrophobic groove of PapK, a pilus subunit, to which the compound recited in claim 138 binds. Figure 6E directs one to "[n]otice the predominance of *hydrophobic residues in the groove* [of PapK], the base of which is part of the hydrophobic core of the protein." Furthermore, the specification, on p. 25, ln. 22-23, discloses that the "base of the groove on the surface of the PapK subunit is formed by the hydrophobic core of the protein."

⁷ Specification, p. 6, ln. 23-26 (disclosing that a "particularly preferred antibacterial compound comprises a peptide comprising an amino-terminal amino acid sequence Ser-Asp-Val-Ala-Phe-Arg-Gly-Asn-Leu-Leu (**SEQ ID NO: 12**) or any related analogues that would **competitively bind to the binding site of a pilus subunit**").

⁸ *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (stating that "anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration").

The Office asserts that the 19mer of Flemmer et al. anticipates formula (I) of claim 1. Specifically, the Office correlates Flemmer et al.'s seven peptide sequence from Gly(19') to Glu(13') to Applicant's Z₂ of claim 1, based upon the previous "peptide analog" language of the claim. But as currently amended, peptide analog has been cancelled and **Claim 1 recites that Z₂ is either a 1 to 5 residue peptide or a bond. As such, Flemmer et al's 7 residue sequence from Gly(19') to Glu(13') does not conform to a sequence with a maximum length of 5 residues.** So, the 19mer polypeptide disclosed in Flemmer et al. does not contain "each and every limitation" possessed by claim 1 and, as such, does not anticipate formula (I) of claim 1. The above argument applies equally to claim 1 and claims dependent thereof, for example, claims 2, 4, 5, 8, 9, and 19. The above argument also applies to claim 16 where Z₁₂ corresponds to Z₂.

The Office also asserts that claims 137-139 are anticipated by Flemmer et al. But each of these claims require the following sequence (SEQ ID NO: 12):

Ser Asp Val Ala Phe Arg Gly Asn Leu Leu

Flemmer et al. does not disclose this sequence. Therefore, Flemmer et al. does not anticipate claims 137-139.

The Office found confusing Applicant's assertions regarding the Thr(7') as a hydrophilic residue corresponding to X₆.⁹ This statement was not an argument per se. Rather, the statement was intended to correct the Office's mistaken classification of a Thr residue as hydrophobic.¹⁰ It is not contested that claim 1 allows X₆ to be hydrophobic or hydrophilic.

C. INFORMALITIES

The Office objected to informalities of subscripted and unsubscripted terms, specifically G1 versus G₁. The claims have been amended to consistently recite G₁. As such, Applicant respectfully requests the Office to withdraw the objection.

⁹ 5/5//04 Office Action, p. 5.

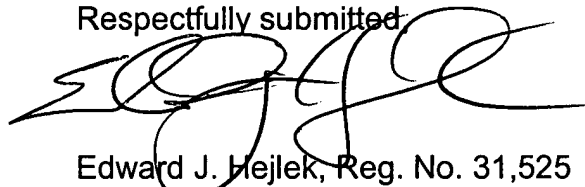
¹⁰ See 9/2/03 Office Action, p. 8.

CONCLUSION

In light of the foregoing, Applicants request an entry of the specification amendment, claim amendments, and abstract amendments; request a withdrawal of claim rejections; and solicit allowance of the claims. The Office is invited to contact the undersigned attorney should any issue remain unsolved.

A check in the amount of \$ 1,125.00 is enclosed. The Commissioner is hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,



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